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Ms. Diane Ford
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Re: Regulation of Doctors of Podiatric Medicine

Dear Ms. Ford:

This letter is a follow-up to the meeting which we attended on December 20, 2002. One of the major topics discussed involved the roles of the Department of Health Services ("DHS" or "the Department") and the Board of Podiatric Medicine ("the Board") with respect to scope of practice issues. In addition, questions were raised concerning the authority of DHS to issue policies in this area. You, in turn, appeared to express some concern about the procedures used by the Board in making scope of practice determinations. You also indicated that DHS needed to have some level of "comfort" regarding these matters.

In order to address this issue in perspective, it is first necessary to discuss the legal authority of both the Board and DHS with respect to scope of practice issues.

A. The Board's Delegated Authority

The Board of Podiatric Medicine has been charged by the Legislature with the responsibility for regulating the profession of podiatric medicine within the State of California. (Business and Professions Code Sections 101.6, 2460, 2460.1 [hereinafter B. & P. Code § 101.6, etc.].) Within the Board's enabling legislation is the statutory definition of "podiatric medicine" (i.e. "scope of practice"). (See

B. & P. Code § 2472.)

In addition, the Board has been delegated the authority by the Legislature to:

> [A]dopt, amend, or repeal, in accordance with the provisions of the Administrative Procedure Act, regulations necessary to enable [it] to carry into effect the provisions of law relating to the practice of podiatric medicine. (B. & P. Code § 2470.)

In light of this statutory authority, there should be no question that the Board, not DHS, is the State agency responsible for issuing regulations (i.e. "policy") concerning the scope of practice of podiatrists. Moreover, this authority is not to be "shared" between the two agencies. It is ***exclusively*** the province of the Board. This point was underscored by the Attorney General of California. In a published opinion, he concluded that:

> Given that the Legislature has defined the scope of practice of non-physician health practitioners in the Business and Professions Code and has provided for the regulation thereof by various boards within the DCA, ***we view the [Department of Health Service's] responsibilities as excluding the regulation of an individual practitioner's scope of practice***. Rather, the Department's duties would include insuring that a particular health facility has adequate equipment and licensed personnel, and is providing the specified services of its license in a satisfactory manner. (63 Ops. A.G. 143, 145 (1980) [Emphasis added].)

B. How DHS Attempts to Define a Podiatrist's Scope of Practice

In previous years, DHS appeared to honor these principles. (See letter dated May 22, 1985 from Paul H. Keller, Chief of the Policy and Support Branch relying on an opinion from DCA Legal Counsel concerning a podiatrist's scope of practice.) Today, DHS may acknowledge these principles in theory, but it has repeatedly violated them in practice. Here are some examples.

1. DHS has establish the following "regulation" forbidding podiatrists from working in Ambulatory Surgery Centers ("ASCs"):

> "A podiatrist's limited training and scope of practice does not meet the requirements and licensure ***intended*** for a physician practicing in an ASC in California." (Letter to Timothy J. Wolf, dated Feb. 1, 2002; Letter to a Redding podiatrist, dated July 3, 2002 [Emphasis added].)

The use of the word "intended" indicates that DHS is making a subjective evaluation concerning a podiatrist's scope of practice. To create this "intention," DHS cited a provision from Federal Regulations which requires Ambulatory Surgery Centers to have "physicians qualified to administer anesthesia." But this requirement is facially neutral with respect to podiatrists. It contains no substantive restrictions on a podiatrist's scope of practice. Rather, podiatrists are included within the meaning of the term "physician" under the Social Security Act. (See 42 U.S.C. § 1395x(r) (Section 1861(r) of the Act).) And obviously under these Federal laws, "physicians" including podiatrists are permitted to practice in Ambulatory Surgery Centers.

Because these facially-neutral standards do not provide legal authority to exclude podiatrists from ASCs, DHS ultimately has to apply and interpret the provision from the statutory definition of "podiatric medicine" found in State law. The provision DHS uses as the basis for its policy is the one which prohibits podiatrists from administering general anesthesia. It then appears that DHS then extrapolated from this unrelated principle that podiatrists are provision an not qualified to perform ***any type of*** practice in Ambulatory Surgery Centers.

2. DHS has determined that a podiatrist cannot conduct an examination of a patient to evaluate the risk or effects of general anesthesia.

DHS has determined that a "podiatrist's ***scope of practice*** does not allow the administration or supervision of the administration of general anesthesia." (Letter to Timothy J. Wolf, dated Feb. 1, 2002, p. 3 [Emphasis added].) DHS then built on this interpretation by issuing yet another one. It concluded that the podiatrist was therefore "not qualified to perform a comprehensive physical examination immediately before surgery to evaluate the patient's ability to tolerate [the] anesthesia." (*Id*.)

DHS also attempted to rationalize this policy by citing 42 C.F.R. § 488.22. This provision of the Code of Federal Regulations requires that physical examinations for admission purposes be conducted by doctors of medicine or osteopathy (M.D.s or D.O.s). But it has nothing to do with Ambulatory Surgery Centers. It governs hospitals. It also governs admission examinations, not those conducted immediately before or after surgery. It is found in Subchapter G of Chapter IV of Title 42. By contrast, regulations governing ASCs are found in Subchapter B. (See enclosed Table of Contents for the Code of Federal Regulations.)

C. Lack of Legal Authority

DHS claims its policies are justified on the grounds of overriding licensing requirements imposed on health care facilities by either State or Federal law. But when these claims are closely scrutinized, they fall apart.

1. 42 C.F.R. § 483.12

DHS has maintained that this section of the Federal Regulations gives it the authority to establish certain rules concerning Ambulatory Surgery Centers. Again, DHS is seeking support in the wrong part of the Code of Federal Regulations. The regulation in question pertains to Long Term Care Facilities, not Ambulatory Surgery Centers. The Table of Contents I have enclosed makes this abundantly clear.

2. Refusal by DHS to recognize admitting privileges of podiatrists at ASCs.

DHS erroneously presumes it has the authority to prevent podiatrists from admitting patients to Ambulatory Surgery Centers in the State of California. In its February 1, 2002 letter to Timothy J. Wolf, DHS states:

> "A podiatrist with admitting privileges with a qualifying hospital does not meet the part 416.41 requirement that the ASC must have a written transfer agreement with a local Medicare participating hospital, or other hospital that meets the requirement for payments for emergency services, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital."

DHS has thus determined that a podiatrist with admitting privileges disqualifies the ASC from Medicare coverage because the podiatrist is not a licensed MD.

The rationalization for this rule is the concept DHS describes as "the intent of the body of regulations." DHS states that:

> "The admitting privileges of the podiatrist who is on the ASC staff, to an appropriate hospital is only part of the requirement of part 416.41, and does not fulfill ***the intent of the body of regulations*** governing an ASC. . . . [A] qualified physician must be present in the ASC to perform admission history and physical . . . ." (*Id*. [Emphasis added])

The "intent of the body of regulations" can mean whatever the eye of the beholder wishes it to be. It is regulation by arbitrary fiat.

Moreover, 42 C.F.R. § 416.41 does not support the position taken by DHS. It purpose is to insure that for patients who are in need of emergency medical care that is beyond the scope of what is available at the ASC can be immediately transferred to a hospital. With respect to such a hospital, Section 416.41 provides among other things that:

> "The ASC must have a written transfer agreement with such a hospital, ***or all physicians performing surgery in the ASC must have admitting privileges at such a hospital***." [Emphasis added.]

Federal Regulations use the term "physician," that includes podiatrists. (42 U.S.C. § 1395x(r).) Thus, Section 416.41 merely requires a written transfer agreement with the hospital or, in the alternative, that all its physicians including whatever podiatrists are on staff have admitting privileges at the hospital.

The notion that podiatrists cannot have admitting privileges because they have a limited scope of practice is a rule which has no legal foundation. Section 416.41 does not appear to say anything about the scope of practice of these podiatrists. Nor, as DHS implies, does it limit admitting privileges because of the fact that podiatrists have a limited scope of practice. What this Section is concerned about is whether such admitting privileges are in place. If they are, the ASC satisfies this particular provision of the Federal Regulations.

D. DHS Policies That Are Contrary to Existing Law

1. Is a Podiatrist a "Physician" entitled to Coverage in an ASC?

DHS	Center for Medicare & Medicaid Services [1]
"A podiatrist is not considered a qualified physician to meet all of the Conditions of Coverage for [an] ASC."	"In section 1861(r) of the Social Security Act the definition of 'physician' includes, 'a doctor of podiatric medicine . . . but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them.' The Conditions of coverage for ASCs (42 CFR 416[C]) do not further define the term 'physician,' ***therefore, a podiatrist is considered a physician for purposes of 42 CFR 416 Subpart C if he or she is performing duties which he or she is legally authorized to perform in accordance with State law***." (Letter to Timothy J. Wolf, Nov. 21, 2001.)

B. & P. Code § 2472(d)(3)

"Surgical treatment by a podiatrist . . . shall be performed only in the following locations: . . . . ***[a]n ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act***, if the podiatrist has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital.…"

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[1]. CMS is an arm of the Dept. of Health and Human Services which issues Medicare law interpretations.

It is evident from Section 2472(d)(3) that the Legislature envisioned podiatrists would be "certified to participate in the Medicare program" and at the same time have surgical privileges at an ambulatory surgical center. This language cannot be squared with the position taken by DHS.

2. Can Podiatrists Having Admitting Privileges at ASC Consistent with Federal Medicare Law?

DHS takes the position that "a podiatrist with admitting privileges with a qualifying hospital" puts an ASC in violation of the Conditions for Coverage found in 42 C.F.R. § 416.41. Federal regulatory agencies apparently do not share this view.

DHS	CMS
"A podiatrist with admitting privileges . . . does not meet the part 416.41 requirement . . . . "	"Q2. Section 416.41 requires the ASC to have a transfer agreement or all physicians performing surgery in the ASC must have admitting privileges in a hospital. Would the requirement be fulfilled if the podiatrist has admitting privileges? A2. If an ASC does not have a written transfer agreement with a local Medicare-participating hospital or a local non-participating that meets the requirements for payments for emergency services, all physicians performing surgery in the ASC must have admitting privileges at such a hospital. ***This requirement includes podiatrists performing surgery in the ASC***. [Emphasis added.]

3. Can Podiatrists Perform Medical Histories and Physical Examinations?

DHS

"The podiatrist's history and physical examination do not fulfill part 416.47(b)(2) requirement that every medical record include significant medical history and results of a physical examination."

CMS

"Federal regulations do not prohibit podiatrists from performing history and physicals. Therefore, it is within the podiatrist's scope of practice ***as defined by California State Law*** to perform complete history and physical examinations (H&P), then an H&P performed by a podiatrist would meet this requirement."

Joint Commission on Accreditation of Healthcare Organizations ("JCAHO")

"Q: Can Podiatrist and Dentist perform the entire history and physical for a patient admitted for inpatient and outpatient care?

"A: Yes, as noted in standard MS. 6.2.2, 'other licensed independent practitioners who are permitted to provide patient care services independently may perform all or part of the medical history and physical examination, if granted such privileges.'

"It is consistent with MS.6.2.2 for a qualified and credentialed Podiatrist or Dentist to independently perform all of the inpatient and outpatient history and physical examination, if given those privileges through the medical staff process, ***subject to applicable state law***."

Legal opinion by Gregory Gorges, DCA Staff Counsel Sept. 22, 1982

"[A] podiatrist may perform a general history and physical examination upon a patient in conjunction with podiatric treatment so long as no conclusion or diagnosis is made regarding the patient's condition except as it relates to that part of the anatomy within the podiatrist's authorized scope of practice."

1. Can Podiatrists Examine Patients for Risks of Anesthesia Immediately Before Surgery?

DHS	CMS
A podiatrist is not a physician qualified to examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed, as required by part 416.42(a)."	"Q3. Section 416.42(a) requires that a physician must examine the patient immediately before surgery to evaluate the risk of anesthesia. May a podiatrist fulfill this requirement? A3. ***Federal regulations do not define the scope of practice for podiatrists. Therefore, if a podiatrist, acting within the scope of his/her practice as defined by California State Law is permitted to perform a complete physical examination and evaluate the risk of the patient receiving general anesthesia, the podiatrist would be qualified to fulfill this requirement***."

E. Issuing Policies Which Are Legal Nullities

It is axiomatic that any regulation issued by a government agency lacking appropriate legal authority is void. (*Ferdig v. State Personnel Bd.*, 71 Cal. 2d 96, 103, 77 Cal. Rptr. 224, 229 (1969); *Aylward v. State Board of Chiropractic Examiners*, 31 Cal. 2d 833, 839, 192 P.2d 929, 933 (1948).) Likewise, regulations or policies utilized by an agency which are contrary to existing statutory law are legal nullities. (*Hodge v. McCall*, 185 Cal. 330, 334, 197 P. 86, 88 (1921); *Graham v. State Bd. Of Control*, 33 Cal. App. 4th 253, 260, 39 Cal. Rptr. 2d 146, 150 (1995) ("Board has no power to adopt a regulation in conflict with or which alters or violates a statute.").)

Based on one or both of these legal principles, I believe it is fair to say that the DHS policies discussed above are legal nullities.

But there is another fundamental and independent reason why these policies are unenforceable. It is found in the Administrative Procedure Act ("APA"). That Act provides that:

> "No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation as defined in Section 11342.600, unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule has been adopted as a regulation and filed with the Secretary of State pursuant to this chapter." (Govt. Code § 11340.5(a).)

In the seminal case of *Grier v. Kizer*, 219 Cal. App. 3d 422, 431, 268 Cal. Rptr. 244, 249 (1990), *disapproved on other grounds in Tidewater Marine Western, Inc. v. Bradshaw*, 14 Cal. 4th 557, 559, 59 Cal. Rptr. 2d 186 (1996), the Court held that:

> "Unless the agency promulgates a regulation in substantial compliance with the APA, the regulation is without legal effect."

> (See also *Armistead v. State Personnel Board*, 22 Cal. 3d 198, 204, 149 Cal. Rptr. 1 (1978) ("rules that interpret and implement other rules have no legal effect unless promulgated in substantial compliance with the APA").)

There is no question but that the pronouncements contained in various DHS letters concerning the scope of practice of podiatrists are rules of general application. In addition, they do not appear to fall under any exception to the APA. (See Govt. Code § 11340.9.) Therefore, the policies being issued by DHS concerning the scope of practice of podiatrists are "regulations" and as such would be subject to the APA rulemaking process. (See Govt. Code §§ 11342.600, 11340.5(a).) In the absence of having such policies undergo the APA rulemaking process, they have no legal effect.

F. The "Comfort Level"

At the December 20th meeting, the issue of a "comfort level" was raised concerning how the Board of Podiatric Medicine makes its policy determinations. I indicated at the meeting, the Board is essentially no different than any other State agency in the manner in which it sets policies. It operates by making either case-by-case determinations or adopting general policy standards. As explained above, general policies are "regulations" and as such require formal adoption pursuant to the provisions of the APA. Case-by-case determinations are delegated to and made by the Executive Officer and staff. Because the Board consists of a number of appointed members, it cannot take any action unless it convenes at a meeting held pursuant to the Bagley-Keene Open Meeting Act. At such meetings, disciplinary matters involving formal administrative actions against licensees are also reviewed and appropriate orders issued. Again, there is nothing novel in any of this and it is all predicated on the Board seeking to follow the applicable provisions of the Government and Business and Professions Codes.

G. Recommended Action

The purpose of this letter is to advise DHS of the Board's position that DHS' continued regulation of matters concerning the scope of practice of podiatrists is without legal foundation. These DHS regulations have had an adverse impact not only on podiatrists but consumers as well. In many instances, these policies appear designed to prevent podiatrists from carrying out what otherwise would be lawful professional practices. This, in turn, significantly impacts the level of medical services available to the public.

The Board requests that DHS immediately rescind all of its illegal policies concerning the scope of practice of podiatrists, particularly those involving ASCs.

Sincerely,

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